



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0585; FRL-9929-27]

Distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear when used as an inert ingredient (solvent, diluent and/or dust suppressant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. On behalf of Pennzoil-Quaker State Company, Wagner Regulatory Associates, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0585, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0585 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0585, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8049) by Wagner Regulatory Associates, P.O. Box 640, 7217 Lancaster Pike, Suite A, Hockessin, DE 19707 on behalf of Pennzoil-Quaker State Company, 700 Milam Street, Houston, TX 77002. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear (CAS Reg. No. 848301-69-9) when used as an inert ingredient as a solvent, diluent and/or dust suppressant in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Wagner Regulatory Associates on behalf of the Pennzoil-Quaker State Company, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human

health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear (also known as GTL petroleum distillates) as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral lethal dose (LD)₅₀ is 5,000 milligrams/kilograms (mg/kg) in rats. An acute dermal toxicity study was not conducted. There were no available dermal irritation data. It is not irritating to the rabbit eye. It is not a skin sensitizer in the guinea pig.

In a 90-day oral toxicity study, GTL petroleum distillates administered by gavage resulted in a statistically significant increase in the incidence and severity of alveolar macrophage accumulations and increased vacuolation of alveolar macrophages in the lung in rats at the lowest observed adverse effect level (LOAEL) 200 mg/kg/day. The No Observed Adverse Effect Level (NOAEL) was 50 mg/kg/day.

In a 2-generation reproductive toxicity study via gavage in rats, GTL petroleum distillates caused maternal and offspring toxicity at 1,000 mg/kg/day. Toxicity was manifested as chronic interstitial/alveolus inflammation in the lungs. The NOAEL for parental toxicity was 50 mg/kg/day since animals in the mid dose (250 mg/kg/day) group were not analyzed. The reproduction NOAEL was 1,000 mg/kg/day, the highest dose tested.

Based upon subsequent studies conducted to evaluate the lung effects, the Agency determined that the effects observed in the 90-day oral toxicity study and 2-generation reproductive toxicity study were caused by gavage administration error and were not test material (dose) related. In a 28-day oral feeding study in rats at doses up to 1,256 mg/kg/day, no adverse effects were observed. In a prenatal developmental toxicity study in the rat (by oral gavage) at doses up to 1,000 mg/kg/day, no adverse toxicological effects were seen. The results of these two more recent studies alleviated the Agency's concern for the lung effects seen in the 90-day oral toxicity study and the 2-generation reproduction study.

GTL petroleum distillates were evaluated for mutagenic potential using the Ames test, micronucleus assay, and gene mutation in mammalian cells. These studies were negative for the

induction of mutations and aberrations. Therefore, GTL petroleum distillates are considered non-mutagenic.

A neurotoxicity study was not conducted with GTL petroleum distillates. However, signs of neurotoxicity were not observed in acute toxicity tests at doses up to 5,000 mg/kg body weight (bw)/day. Evidence of neurotoxicity was not observed in the 90-day oral toxicity study in rats and in the 28-day oral feeding study in rats.

An immunotoxicity study was not conducted with GTL petroleum distillates. However, alveolar macrophage accumulations and increased vacuolation of alveolar macrophages in the lung was observed in rats at >200 mg/kg/day in both the 90-day oral and 2-generation reproduction toxicity studies. However, these effects were determined to be caused by gavage technique error rather than effects attributable to the test substance.

There are no data specific to the absorption, metabolism, distribution and elimination of GTL petroleum distillates, however, the absorption of other mixtures of normal, branched and cyclic petroleum derived hydrocarbons is inversely related to carbon chain length and is independent of isomeric form, preparation process or type of product. Consequently, when administered orally, Fischer-Tropsch derived hydrocarbons in the range of C₁₈-C₅₀ are likely to be unabsorbed and excreted in the feces.

Carcinogenicity studies with GTL petroleum distillates are not available for review. However, based on the lack of carcinogenicity of related linear, branched, and cyclic alkanes and the negligible absorption of GTL petroleum distillates, lack of systemic toxicity at the limit dose, lack of mutagenic concerns, GTL petroleum distillates are not expected to be carcinogenic.

B. Toxicological Points of Departure/Levels of Concern

There were no adverse effects in repeat dose toxicity, reproductive, and developmental studies with GTL petroleum distillates at or above limit dose levels to either parental animals or

their offspring. Thus, due to the low potential hazard and lack of hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for GTL petroleum distillates.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses and drinking water.* In evaluating dietary exposure to GTL petroleum distillates, EPA considered exposure under the proposed exemption from the requirement of a tolerance. Dietary exposure to GTL petroleum distillates can occur when eating food treated with pesticide formulation containing this inert ingredient. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment for GTL petroleum distillates was not conducted.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

GTL petroleum distillates may be used as an inert ingredient in agricultural pesticide products that could result in short- and intermediate-term residential exposure. Residential exposure can occur via dermal and inhalation routes of exposure to residential applicator. Dermal and inhalation exposure can occur from the use of consumer products and foods/food additives containing GTL petroleum distillates. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for GTL petroleum distillates was not conducted.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative

effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear to share a common mechanism of toxicity with any other substances, and the category does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

At this time, there is no concern for potential sensitivity to infants and children resulting from exposures to GTL petroleum distillates. There is no reported quantitative or qualitative evidence of increased susceptibility of rat fetuses to in utero exposure to GTL petroleum distillates in developmental toxicity studies in rats. No quantitative or qualitative evidence of increased susceptibility has been reported following the pre/postnatal exposure to rats in 2-

generation reproduction toxicity studies in rats. Given the lack of adverse toxicological effects at limit dose levels, a safety factor analysis has not been used to assess the risk. For these reasons the additional tenfold safety factor is unnecessary.

E. Aggregate Risks and Determination of Safety

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. Dietary (food and drinking water) and non-dietary (residential) exposures of concern are not anticipated for GTL petroleum distillates because of its low toxicity based on animal studies showing toxicity at or above the limit dose of 1,000 mg/kg/day. Taking into consideration all available information on GTL petroleum distillates, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to GTL petroleum distillates under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of GTL petroleum distillates when used as an inert ingredient (solvent, diluent and/or dust suppressant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for distillates, (Fischer-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear (CAS Reg. No. 848301-69-9) when used as an inert ingredient (solvent, diluent and/or dust suppressant) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does

not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient “Distillates, (Fishcher-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear (CAS Reg. No. 848301-69-9)” to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	* * *
Distillates, (Fishcher-Tropsch), heavy, C ₁₈ -C ₅₀ , branched, cyclic and linear (CAS Reg. No. 848301-69-9)		Solvent, diluent and/or dust suppressant
* * *	*	* * *